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**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF NEW JERSEY**

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NOVARTIS PHARMACEUTICALS )  
CORPORATION )  
Plaintiff, )  
v. ) Civil Action No. \_\_\_\_\_  
LUPIN LTD. and LUPIN )  
PHARMACEUTICALS, INC., )  
Defendants. )  
\_\_\_\_\_  
)

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**COMPLAINT**

Plaintiff Novartis Pharmaceuticals Corporation (“Novartis”), by its undersigned attorneys, brings this action against Defendants Lupin Ltd. and Lupin Pharmaceuticals, Inc. (“Lupin Inc.”; collectively “Lupin”), and hereby alleges as follows:

**Nature of the Action**

1. This is an action for infringement of United States Patent No. 6,294,197 (the “197 patent”) under the Patent Laws of the United States, 35 U.S.C. §100 *et seq.*, particularly §271(e)(2).

2. This action relates to Defendants' filing Abbreviated New Drug Application ("ANDA") No. 78-946 with the United States Food and Drug Administration ("FDA"), seeking approval to commercially market generic versions of Novartis's DIOVAN HCT® drug product in the United States, including New Jersey.

**The Parties**

3. Plaintiff Novartis is a corporation organized and existing under the laws of Delaware, with a principal place of business at One Hanover Health Plaza, East Hanover, New Jersey 07936.

4. On information and belief, Lupin Ltd. is a company organized and existing under the laws of India, having a principal place of business at B/4 Laxami Towers, Branda Kurla Complex, Bandra (East), Mumbai, Maharashtra 400 051, India.

5. On information and belief, Lupin Inc. is a corporation organized and existing under the laws of Virginia, having a principal place of business at Harbor Place Tower, 111 South Calvert Street, 21st floor, Baltimore, Maryland 21202.

6. On information and belief, Lupin Ltd. and Lupin Inc., acting in their own individual capacities and/or in privity and/or concert with one another, are in the business of making and selling pharmaceutical products in the United States, including New Jersey.

**Subject Matter Jurisdiction and Venue**

7. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338.

8. Venue is proper in the judicial district pursuant to 28 U.S.C. §§ 1391(b, c) and/or 1400(b).

**Personal Jurisdiction**

9. On information and belief, Lupin Ltd. and Lupin Inc. operate as an integrated, unitary business. For example, in its 2011 Annual Report, Lupin Ltd. identifies Lupin Inc. as a wholly-owned subsidiary and ascribes this subsidiary's activities to "the Company," *i.e.*, Lupin Ltd.

10. The Annual 2011 Report also provides consolidated financial information, treating Lupin Ltd. and its various subsidiaries (including Lupin Inc.) and associates as a "Group," and reports that annual revenues in the US for 2011 exceeded \$400 million dollars.

11. Lupin Ltd. maintains a web-site at the uniform resource locator (URL) <http://www.lupinworld.com>. The web-site's "/businesssegment.htm" page reflects that the company divides its "formulation business" into seven regional markets, including the "USA" and identifies Lupin Inc. as the entity responsible for the U.S. market. The "/contact.htm#formulation" page of the web-site further indicates that Lupin Inc. is Lupin Ltd.'s "American" contact within the company's "Global Pharmaceutical Business."

12. Lupin Inc. also maintains a web-site at the uniform resource locator (URL) <http://www.lupinpharmaceuticals.com>. According to that web-site's "/mission.htm" page, the company's mission and vision is to "capitalize on the strengths of [its] parent company, Lupin Limited," and be positioned "for growth in the US market."

13. On information and belief, Lupin Ltd. and Lupin Inc., acting in their own individual capacities and/or in privity and/or concert with one another, developed generic copies

of Novartis's DIOVAN HCT® drug product, and seek approval from the FDA to sell the same throughout the United States, including New Jersey.

14. On information and belief, Lupin Ltd., with the assistance of Lupin Inc. and/or for the benefit of Lupin Inc. and/or itself, filed an ANDA No. 78-946, and prepared Paragraph IV Notice letters to Novartis regarding infringement of the '197 patent.

15. Lupin Ltd. and Lupin Inc., acting in their own individual capacities and/or in privity and/or concert with one another, committed the tortious act of patent infringement pursuant to 35 U.S.C. §271(e)(2)(A) that has led to foreseeable harm and injury to Novartis, a New Jersey-based corporation, by filing ANDA No. 78-946.

16. On information and belief, Lupin Ltd., in its own individual capacity and/or via those it acts in privity and/or concert with, including Lupin Inc., regularly does and solicits business in New Jersey, engages in other persistent courses of conduct in New Jersey, and/or derives substantial revenue from services or things used or consumed in New Jersey. These facts demonstrate that Lupin Ltd. has continuous and systematic contacts with New Jersey.

17. On information and belief, Lupin Ltd., in its own individual capacity and/or via those it acts in privity and/or concert with, including Lupin Inc., conducts business in New Jersey.

18. On information and belief, Lupin Ltd., in its own individual capacity and/or via those it acts in privity and/or concert with, including Lupin Inc., derives substantial revenue from sales of pharmaceutical products in New Jersey.

19. On information and belief, Lupin Ltd., in its own individual capacity and/or via those it acts in privity and/or concert with, including Lupin Inc., has entered into contracts with and/or purchased goods or services from persons located in New Jersey.

20. On information and belief, Lupin Inc., in its own individual capacity and/or via those it acts in privity and/or concert with, regularly does and solicits business in New Jersey, engages in other persistent courses of conduct in New Jersey, and/or derives substantial revenue from services or things used or consumed in New Jersey. These facts demonstrate that Lupin Inc. has continuous and systematic contacts with New Jersey.

21. On information and belief, Lupin Inc., in its own individual capacity and/or via those it acts in privity and/or concert with, conducts business in New Jersey.

22. On information and belief, Lupin Inc., in its own individual capacity and/or via those it acts in privity and/or concert with, derives substantial revenue from sales of pharmaceutical products in New Jersey.

23. On information and belief, Lupin Inc., in its own individual capacity and/or via those it acts in privity and/or concert with, has entered into contracts with and/or purchased goods or services from persons located in New Jersey.

24. On information and belief, Lupin Ltd. and Lupin Inc. have each previously submitted to this Court's jurisdiction.

25. On information and belief, both Lupin Ltd. and Lupin Inc. have engaged the services of New Jersey law firms to represent them and entered this District to litigate claims and/or counterclaims before this Court.

26. On information and belief, if Lupin Ltd. were not subject to the jurisdiction of the courts of general jurisdiction of the State of New Jersey, then it would, likewise, not be subject to the jurisdiction of the courts of general jurisdiction of any other state, thereby rendering it amenable to personal jurisdiction in New Jersey based on its aggregate contacts with the United States, as authorized by Federal Rule of Civil Procedure 4(k)(2).

**The Patents in Suit**

27. The '197 patent was duly and lawfully issued on September 25, 2001 to inventors Robert Wagner, Yoshimitsu Katakuse, Takashi Taise, Fujiki Yamato and Manfred Kohlmeyer. A true and correct copy of the '197 patent is attached hereto as Exhibit A. Novartis is the owner by assignment of all rights, title and interest in and to the '197 patent.

**The DIOVAN HCT® Product**

28. Novartis holds an approved New Drug Application ("NDA") under Section 505(a) of the Federal Food, Drug and Cosmetic Act (the "FFDCA"), 21 U.S.C. §355(a), for film-coated tablets of varying dosage strengths comprising valsartan (80, 160 or 320 mg) and hydrochlorothiazide ("HCT"; 12.5 or 25 mg), which are sold under the trade name DIOVAN HCT®. The claims of the '197 patent cover, *inter alia*, DIOVAN HCT®, its method of manufacture, and its use.

29. Pursuant to 21 U.S.C. § 355(b) and attendant regulations, the '197 patents has been listed in the FDA publication, "Approved Drug Products with Therapeutic Equivalence Evaluations" (the "Orange Book"), with respect to DIOVAN HCT®.

**Acts Giving Rise To This Action**

30. On information and belief, Lupin Ltd. and/or Lupin Inc. review(s) US patents and seek(s) opportunities to challenge those patents.

31. On information and belief, Lupin Ltd. and/or Lupin Inc. reviewed the '197 patent and certain commercial and economic information relating to DIOVAN HCT®, including estimates of the revenues generated by the sale of DIOVAN HCT®, and decided to file an ANDA, seeking approval to market amlodipine besylate/valsartan/HCT tablets in the United States, including New Jersey.

32. On information and belief, Lupin Ltd., on its own behalf and/or on behalf of Lupin Inc., submitted ANDA No. 78-946 to the FDA under §505(j) of the FFDCA, 21 U.S.C. §355(j). That ANDA seeks FDA approval, *inter alia*, for the commercial marketing in the United States, including New Jersey, of generic forms of DIOVAN HCT® that are of base-equivalent strength (the “Lupin Generic Products”). The ANDA also seeks FDA approval to market the Lupin Generic Products prior to the expiration of the '197 patent.

33. Pursuant to §505(j)(2)(A)(vii)(IV) of the FFDCA, and in ANDA 78-946, Lupin Ltd., on its own behalf and/or on behalf of Lupin Inc., alleged that the claims of the '197 patent would not be infringed by the manufacture, use, offer sale, and/or sale in; and/or importation into the United States, including New Jersey, of the Lupin Generic Products.

34. Novartis received written notification of the ANDA and of the §505(j)(2)(A)(vii)(IV) allegations on or about July 18, 2007 and July 6, 2012. The Paragraph IV

letters state that Lupin Ltd. has submitted data to the FDA regarding the alleged “bioavailability and bioequivalence” of the Lupin Generic Products and DIOVAN HCT®.

35. The stated purpose of the Paragraph IV letters was to notify Novartis that Lupin Ltd. had filed certification with the FDA, under 21 C.F.R. §314.95(c)(1) and in conjunction with ANDA 78-946, for approval, *inter alia*, to commercially manufacture and sell generic versions of Novartis’s DIOVAN HCT®. The Paragraph IV letters state that activities associated with the manufacture, use, offer for sale, sale or importation of the Lupin Generic Products would not infringe any valid claim of the ’197 patent.

36. The Paragraph IV letters fail to comply with the requirements of §505 (j)(2)(B)(iv)(II) of the FFDCA because, *inter alia*, it contains very limited information about the Lupin Generic Products, their composition, method of manufacture, or methods of use.

37. On information and belief, Lupin Ltd. and/or Lupin Inc. continue(s) to seek and desire approval of ANDA 78-946 from the FDA.

38. On information and belief, Lupin Ltd. and/or Lupin Inc. have/has made, and continue(s) to make substantial preparations to manufacture for; offer for sale, and/or sell in; and/or import into the United States the Lupin Generic Products prior to the expiration of the ’197 patent.

39. On information and belief, Lupin Ltd. and/or Lupin Inc. has/have every intention of manufacturing for and/or in; offering for sale, and/or selling in; and/or importing into the United States the Lupin Generic Products prior to the expiration of the ’197 patent.

40. Because Lupin's second Paragraph IV certification issued on or about July 6, 2012 and relates to a change in the Lupin Generic Products that are the subject of ANDA No. 78-946, Novartis is entitled to a 30-month stay in the approval of the Lupin Generic Products, pursuant to Section 505(j)(5)(B)(iii) of the FFDCA, 21 U.S.C. Section 355(j)(5)(B)(iii).

**COUNT I**

**(Infringement of the '197 Patent under 35 U.S.C. §271(e)(2))**

41. Paragraphs 1-40 are incorporated herein as set forth above.

42. By submitting ANDA No. 78-946, Lupin Ltd. and Lupin Inc. committed an act of infringement with respect to the '197 patent under 35 U.S.C. §271(e)(2)(A).

43. Unless enjoined by this Court, Lupin Ltd. and/or Lupin Inc., upon the approval of ANDA No. 78-946, will infringe the '197 patent under 35 U.S.C. §271 by making, using, offering for sale, and/or selling in; and/or importing into the United States the Lupin Generic Products upon the expiration of the 30-month stay to which Novartis is entitled under §505(j)(5)(B)(iii) of the FFDCA, 21 U.S.C. §355(j)(5)(B)(iii).

44. Lupin Ltd. and Lupin Inc. had notice of the '197 patent prior to filing ANDA No. 78-946. Any infringement of the '197 has been and will be willful and deliberate.

**Injunctive Relief**

45. Novartis will be irreparably harmed if Lupin Ltd. and/or Lupin Inc. are not enjoined by this Court, following the expiration of the 30-month stay. Novartis does not have an

adequate remedy at law to redress any acts of infringement Lupin Ltd. and/or Lupin engage in with respect to the Lupin Generic Products.

**Prayer for Relief**

Novartis respectfully prays for the following relief:

- a. A judgment that Lupin Ltd. and Lupin Inc. have infringed one or more claims of the '197 patent;
- b. An Order that the effective date of any FDA approval of ANDA No. 78-946 be a date that is not earlier than the expiration of the '197 patent, or any expiration of exclusivity to which Novartis is or becomes entitled;
- c. Preliminary and permanent injunctions enjoining Lupin Ltd., Lupin Inc., officers, agents, attorneys and employees of the same, and those acting in privity or concert with the same, from making, using, offering for sale, and/or selling in; and/or importing into the United States the Lupin Generic Products until after the expiration of the '197 patent, inclusive of any patent term extensions and/or exclusivities to which Novartis is or becomes entitled;
- d. A declaration that the commercial manufacture use, offer for sale, and/or sale in; and/or importation into the United States of the Lupin Generic Products prior to patent expiry will directly infringe, induce and/or contribute to infringement of the '197 patent;
- e. If Lupin Ltd., Lupin Inc., or anyone acting in privity or concert with any of them engage(s) in the commercial manufacture, use, sale and/or offer for sale; and/or importation of the Lupin Generic Products prior to the expiration of the '197 patent, a Judgment

awarding damages to Novartis for infringement of the '197 patent, increased to treble the amount found or assessed, together with interest;

- f. A declaration that this case is exceptional, entitling Novartis to recover its reasonable attorney fees pursuant to 35 U.S.C. §§271(e)(4) and 285;
- g. Costs and expenses in this action; and
- h. Such further relief as this Court may deem just and proper.

Dated: July 20, 2012

s/William J. O'Shaughnessy  
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**CERTIFICATION PURSUANT TO L. CIV. R. 11.2**

I certify that to the best of my knowledge, the matter in controversy is not the subject of any other action pending in any other court or of any pending arbitration or administrative proceeding.

Dated: July 20, 2012

s/William J. O'Shaughnessy  
William J. O'Shaughnessy  
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